REMARKS

The present application is a Continued Prosecution Application of Serial No. 09/582,808. The Official Action dated November 20, 2002 issued in the parent application has been carefully considered. Accordingly, the changes presented herewith, taken with the following remarks, are believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, claims 42-83 are amended to omit the double hyphens at the beginning and end of the claims as suggested by the Examiner. Claims 42 and 63 have also been amended to more clearly recite that the Capturer is anchored to the matrix "by", rather than "via", immobilized particles in response to the Examiner's comments set forth in the Official Action, and to further define the particles in accordance with the specification at page 3, lines 19-26. Claims 44-46 have also been amended to more clearly recite a mixture of biospecific affinity reactants and claims 60 and 81 have been amended to more clearly recite a reactant to which the Capturer is capable of binding by biospecific affinity, these changes also being made in response to the Examiner's comments set forth in the Official Action. Claim 47 is amended to correct a typographical error. Finally, claims 50 and 71 have been amended to include limitations from claims 52 and 55. A Version With Markings Showing Changes Made is attached. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

Claims 42-83 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In claims 42 and 63, the Examiner asserted that "via" was vague and indefinite, in claim 43, the Examiner asserted that the term "complex mixture" was vague and indefinite and in claims 60 and 81, the Examiner asserted that the phrase "may bind" was vague and indefinite.

This rejection is traversed and reconsideration is respectfully requested. More particularly, claims 42 and 63 recite that the Capturer is anchored to the matrix by immobilized particles, and the term "via" has been omitted from these claims. Although claim 43 does not contain the term "complex mixture", claims 44-46 now omit the term "complex" and therefore refer to immobilization of a mixture of biospecific affinity reactants. Finally, claims 60 and 81 have been amended to recite a reactant to which the Capturer is "capable of binding" by biospecific affinity, and omit the phrase "may bind". It is therefore submitted that these claims are definite in accordance with the requirements of 35 U.S.C. §112, second paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Claims 42-47, 51-53, 56, 57, 59-61, 63-68, 72-74, 77, 78 and 80-82 were rejected under 35 U.S.C. §103(a) as being unpatentable over the Charlton et al U.S. Patent No. 5,989,921 in view of the Porrvik U.S. Patent No. 5,902,834. The Examiner asserted it would have been obvious to incorporate hydrophilic particles as taught by Porrvik into the method of Charlton et al because Porrvik teaches that these particles can be used as a solid phase in immunoassays, particularly when the particles are in a hydrophilic form. The Examiner further asserts that Porrvik show that the particles will result in an improved flow through the particles which in turn results in improved kinetics.

Claims 48 and 69 were rejected under 35 U.S.C. §103(a) as being unpatentable over Charlton et al and Porrvik in view of the Devlin et al U.S. Patent No. 5,846,703. The Examiner asserted it would have been obvious to incorporate the use of immobilized antigens as taught by Devlin et al into the modified method of Charlton et al. Claims 49, 58, 70 and 79 were rejected under 35 U.S.C. §103(a) as being unpatentable over Charlton et al and Porrvik in view of the Dafforn et al U.S. Patent No. 4,981,786. The Examiner asserted it would have been obvious to incorporate the application of reagents and the detection of

autoimmune antibodies as taught by Dafforn et al into the modified method of Charlton et al. Claims 50, 54, 55, 71, 75 and 76 were rejected under 35 U.S.C. §103(a) as being unpatentable over Charlton et al and Porrvik in view of the Brown et al U.S. Patent No. 5,149,622. The Examiner asserted it would have been obvious to incorporate particles which have a smaller diameter than that of the matrix as taught by Brown et al into the method of Charlton et al. Finally, claims 62 and 83 were rejected under 35 U.S.C. §103(a) as being unpatentable over Charlton et al and Porrvik in view of the Self U.S. Patent No. 4,446,231. The Examiner asserted it would have been obvious to use immunoassays as taught by Self for the diagnosis of autoimmune diseases.

However, Applicants submit that the methods and test kits defined by claims 42-83 are nonobvious over and patentably distinguishable from the combination of Charlton et al and Porrvik, even in further view of Devlin et al, Dafforn et al, Brown et al or Self. Accordingly, these rejections are traversed and reconsideration is respectfully requested.

More particularly, as defined by claim 42, the method of the present invention is for use in a flow matrix which utilizes biospecific affinity reactions to detect an analyte in a sample. The method comprises allowing the sample comprising the analyte and an analytically detectable reactant (Reactant*) to migrate through channels in a flow matrix to a detection zone located in the matrix, in which there is a firmly anchored biospecific affinity reactant (Capturer), and capturing the Reactant* in the detection zone in an amount related to the amount of analyte in the sample. According to claim 63, the invention is directed to a test kit used for performing analytical methods in a flow matrix utilizing biospecific affinity reactions to detect an analyte in a sample. The kit comprises (i) a flow matrix having a detection zone in which there is firmly anchored biospecific affinity reactant (Capturer), and (ii) an analytically detectable reactant (Reactant*).

In both the claimed methods and test kits, the Reactant* has labeled particles as an analytically detectable group, and the Capturer is anchored to the matrix by immobilized particles which exhibit hydrophilic groups on their surface. The particles anchoring the Capturer have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix and do not interfere with detection of Reactant* in the detection zone. Thus, the Capturer is predisposed in the flow channels of the flow matrix by the immobilized particles exhibiting hydrophilic groups on their surface. As set forth in the present specification, including the examples, such methods and test kits wherein the Reactant* has labeled particles as an analytically detectable group and the Capturer is anchored within the flow channels of the matrix by immobilized particles which exhibit hydrophilic groups on their surface, provide surprisingly improved analytical detection of an analyte in a sample.

Charlton et al disclose a test cell and a method for detection of a preselected ligand in a liquid sample. Charlton et al disclose that the method involves the step of transporting the sample and a conjugate comprising a protein bound to a metal sol or other colored particle along a flow path and in contact with a test site comprising immobilized binding protein specific to an epitope of the ligand. Charlton et al broadly disclose that the test site comprises latex particles trapped or otherwise fixed in the flow path having the immobilized protein on their surface (column 3, lines 25-37), and specifically disclose the use of latex beads comprising polystyrene particles passively coated with purified rapid anti-human chorionic gonadotropin (column 7, lines 61-64).

However, Applicants find no teaching or suggestion by Charlton et al relating to a method or test kit as defined in claims 42 and 63 wherein a biospecific affinity reactant (Capturer) is firmly anchored to a flow matrix via immobilized particles exhibiting hydrophilic groups on their surface, particularly in combination with an analytically detectable reactant (Reactant*) having labeled particles as an analytically detectable group.

As discussed in the present specification, for example beginning at page 4, line 21, a hydrophobic particle such as the polystyrene employed by Charlton et al is absorbed very strongly to flow matrices such as nitrocellulose membranes. However, the hydrophobic features of the particles promote non-specific absorption of an analytically detectable reactant (Reactant*) and/or analyte and therefore decrease the sensitivity of test methodologies. In the present invention, the immobilized particles which anchor the Capturer to the matrix exhibit hydrophilic groups on their surface. As discussed beginning at page 5, line 8, introduction of the hydrophilic groups on the particles facilitates covalent binding of biospecific affinity reactants to the particles and decreases the tendency of non-specific absorption in the detection zone. Applicants find no teaching or suggestion by Charlton et al relating to immobilized particles exhibiting hydrophilic groups on their surface, or any advantage provided thereby.

The deficiencies of Charlton et al are not resolved by Porrvik. That is, Porrvik discloses a method of producing open porous spherical particles by polymerizing monovinyl monomers and divinyl monomers and/or polyvinyl monomers in an emulsion with the aid of an initiator. Porrvik broadly discloses at column 1 that the particles can be used as a supportive matrix in chromatography and in the solid-phase synthesis of oligopeptides and oligonucleotides and also as microcarriers in the cultivation of cells, e.g., anchorage-dependent cells, and as a solid phase in heterogenic immunoassays, particularly when the particles are in a hydrophilic form.

However, Applicants find no further teaching or suggestion by Porrvik relating to such uses, and particularly Applicants find no teaching or suggestion by Porrvik that the particles manufactured according to her method are suitable for use in immunoassays employing a flow matrix. At best, Porrvik's reference to immunoassays may suggest to one skilled in the art to try to use the disclosed particles as the solid phase, i.e., by adding the

particles to a liquid sample for assay of the sample. Additionally, Applicants find no teaching or suggestion by Porrvik that the particles prepared according to her method are suitable for immobilization on a flow matrix or that a Capturer may be anchored to a flow matrix by such immobilized particles. Moreover, it is not obvious to one of ordinary skill in the art that particles as disclosed by Porrvik could be used in a flow matrix. Applicants find no teaching or suggestion by Porrvik relating to use of particles as required by claims 42 and 63, having a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix and not interfering with detection of Reactant* in the detection zone. Finally, Applicants find no teaching by Porrvik that introduction of hydrophilic groups on particles as employed by Charlton et al will facilitate covalent binding of biospecific affinity reactants to the particles in a flow matrix which utilizes biospecific affinity reactions to detect an analyte in a sample, and decreases the tendency of non-specific absorption in the detection zone.

The Examiner asserts that since Porrvik shows improved flow through the disclosed particles, resulting in improved kinetics, the combination asserted by the Examiner would have been obvious to one of ordinary skill in the art. However, Applicants find no teaching or suggestion by Charlton et al relating to the use of porous particles or regarding any reaction kinetics dependent on porous particles. In fact, the improved flow desired by Porrvik would be disadvantageous in the device of Charlton et al as flow through the porous particles may undesirably result in capture of detection conjugate in the pores. Thus, Applicants find no motivation in either Charlton et al or Porrvik for combining their teachings along the lines asserted by the Examiner.

The mere fact that prior art could be modified to result in a claimed invention does not make the modification obvious unless the prior art suggested the desirability of the modification, *In re Mills*, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990), *In re Fritch*, 23 U.S.P.Q.2d 1780 (Fed. Cir. 1992). Applicants find no suggestion regarding the desirability of

modification asserted by the Examiner. Thus, the combination of Charlton et al and Porrvik does not render the presently claimed methods and test kits obvious. It is therefore submitted that the rejection of claims 42-47, 51-53, 56, 57, 59-61, 63-68, 72-74, 77, 78 and 80-82 under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

Moreover, the deficiencies of Charlton et al in view of Porrvik are not resolved by any of the tertiary references cited by the Examiner. For example, Devlin et al disclose fluorescence immunoassays using fluorescent dyes free of aggregation and serum binding. Devlin et al broadly disclose that the sandwich techniques disclosed therein can be used to assay antibodies rather than antigens wherein the antigen coupled to a solid phase is used as a first receptor. Beginning at column 4, line 56, Devlin et al briefly discuss the use of enzyme-enhanced fluorescence technology which combines microparticle capture and antigen-antibody reaction with an enzyme rate reaction using a fluorescent enzyme substrate.

However, Applicants find no teaching or suggestion by Devlin et al relating to a method or test kit as presently claimed, or for modifying the teachings of Charlton et al to provide such a method or test kit. Particularly, Applicants find no teaching or suggestion by Devlin et al for a method or test kit employing a flow matrix as presently claimed wherein an analytically detectable reactant (Reactant*) has labeled particles as an analytically detectable group and a biospecific affinity reactant (Capturer) is anchored to the flow matrix via immobilized particles as claimed and exhibiting hydrophilic groups on their surface. Similarly, Applicants find no teaching or suggestion by Devlin for modifying the teachings of Charlton et al to provide such a combination, or relating to any benefit provided by either a flow matrix method or test kit employing such a combination.

In order to render a claimed invention obvious, the prior art must enable one skilled in the art to make and use the claimed invention, *Motorola, Inc. v. Interdigital Tech. Corp.*, 40 U.S.P.Q.2d 1481, 1489 (Fed. Cir. 1997). The cited combination of Charlton et al, Porrvik

and Devlin et al does not enable one skilled in the art to conduct the claimed methods or to make and use the claimed test kits. Thus, these references do not in combination render the presently claimed methods and test kits obvious. It is therefore submitted that the rejection under 35 U.S.C. §103 based on Charlton et al, Porrvik and Devlin et al has been overcome. Reconsideration is respectfully requested.

Dafforn et al disclose a multiple port assay device for capturing a first member of a specific binding pair in a zone and for allowing liquid to be transported by capillary action away from the zone. Delivery of a sample may be made into the device through a first means using a dropper, syringe needle, etc., resulting in deposit of the sample on a bibulous strip, and a liquid reagent other than sample may be added to the device through a second means. Additional liquid reagents may be added to the device either before or after sample addition, at least one of such reagents being added through the means not used for adding the sample (column 13, lines 32-42).

However, Applicants find no teaching or suggestion by Dafforn et al relating to a method or test kit as presently claimed employing, in combination, an analytically detectable reactant (Reactant*) having labeled particles as an analytically detectable group and a Capturer which is anchored to the matrix by immobilized particles as defined and exhibiting hydrophilic groups on their surface. Similarly, Applicants find no teaching or suggestion by Dafforn et al relating to any improvement provided by a method or a test kit employing such a Reactant* and immobilized Capturer in combination. Finally, Applicants find no teaching or suggestion for modifying the teachings of Charlton et al to incorporate any or all of the teachings of Dafforn et al, and particularly Applicants find no teaching or suggestion in either reference for modifying the teachings of Charlton et al along the lines of the presently claimed methods and test kits. In view of these deficiencies in the teachings of Charlton et al, Porrvik and Dafforn et al, the combination of these references does not enable one of

ordinary skill in the art to perform the presently claimed methods or to make and use the claimed test kits. Thus, the combination of Charlton et al, Porrvik and Dafforn et al does not render the presently claimed methods and test kits obvious under 35 U.S.C. §103. It is therefore submitted that the rejection under 35 U.S.C. §103 based on Charlton et al, Porrvik and Dafforn et al has been overcome. Reconsideration is respectfully requested.

Brown et al disclose a material and device usable in solid-phase binding assays. The material comprises a porous matrix of fibers and a plurality of substantially spherical, solid particles having an average diameter of from about 0.1 to about 5 microns and less than the average pore size of the matrix. The particles are retained and immobilized upon the fibers of the matrix and have a substance capable of reaction with an analyte on their surfaces. As described at column 9, line 64 - column 10, line 7, Brown et al disclose a method wherein antibody or antigen is retained upon the particles, followed by application of a test sample containing antigen or antibody to be determined, application of an enzyme-conjugated antibody or antigen, washing, and application of an indicator substance which in the presence of the enzyme portion of the conjugate produces a detectable color or other response.

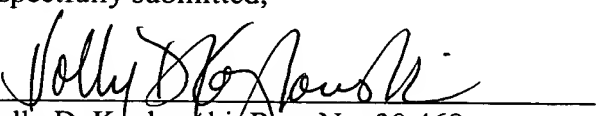
However, Applicants find no teaching or suggestion by Brown et al relating to a method or test kit as presently claimed employing, in combination, an analytically detectable reactant (Reactant*) having labeled particles as an analytically detectable group and a Capturer which is anchored to the matrix by immobilized particles as defined and exhibiting hydrophilic groups on their surface. Similarly, Applicants find no teaching or suggestion by Brown et al relating to any improvement provided by a method or a test kit employing such a reactant and immobilized Capturer in combination. Finally, Applicants find no teaching or suggestion for modifying the teachings of Charlton et al to incorporate any or all of the teachings of Brown et al, and particularly Applicants find no teaching or suggestion in either reference for modifying the teachings of Charlton et al along the lines of the presently

claimed methods and test kits. In view of these deficiencies, the combination of Charlton et al, Porrvik and Brown et al does not enable one of ordinary skill in the art to perform the presently claimed methods or to make and use the claimed test kits. Thus, the combination of Charlton et al, Porrvik and Brown et al does not render the presently claimed methods and test kits obvious under 35 U.S.C. §103. It is therefore submitted that the rejection under 35 U.S.C. §103 based on Charlton et al, Porrvik and Brown et al has been overcome. Reconsideration is respectfully requested.

Finally, Self discloses an immunoassay using an amplified cyclic detection system. At column 1, beginning at line 39, Self broadly discloses that immunoassays may be used for qualitative or quantitative determinations and that color reactions and precipitation reactions, for example, using latex particles for visualization, may be used. However, Applicants find no teaching or suggestion by Self relating to methods or test kits as presently claimed employing a combination of an analytically detectable reactant (Reactant*) having labeled particles as an analytically detectable group and a biospecific affinity reactant (Capturer) anchored to a flow matrix via immobilized particles which exhibit hydrophilic groups on their surface. Similarly, Applicants find no teaching or suggestion by self for modifying the teachings of Charlton to provide such methods or test kits, or relating to any advantage provided thereby. Thus, the combination of Charlton et al, Porrvik and Self does not enable one of ordinary skill in the art to conduct the presently claimed methods or to make and use the presently claimed test kits. Accordingly, the combination of Charlton et al, Porrvik and Self does not render the presently claimed methods and test kits obvious. It is therefore submitted that the rejection under 35 U.S.C. §103 based on Charlton et al, Porrvik and Self has been overcome. Reconsideration is respectfully requested.

It is believed that the above represents a complete response to the rejections under 35 U.S.C. §§ 103 and 112, second paragraph, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

By 

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VERSION WITH MARKINGS SHOWING CHANGES MADE

Claims 42-83 are amended as follows:

[--]42. (Amended) A method for use in a flow matrix, which utilizes biospecific affinity reactions to detect an analyte in a sample, and which comprises:

i. allowing the sample comprising the analyte and an analytically detectable reactant (Reactant*) to migrate through flow channels in a flow matrix to a detection zone (DZ) located in the matrix, in which there is a firmly anchored biospecific affinity reactant (Capturer), and

ii. capturing the Reactant* in the DZ in an amount related to the amount of analyte in the sample,

wherein

A) the Reactant* has labeled particles as an analytically detectable group, and

B) the Capturer is anchored to the matrix [via] by immobilized particles which exhibit hydrophilic groups on their surface, wherein the particles anchoring the Capturer have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix and do not interfere with detection of Reactant* in the detection zone.[--]

[--]43. (Amended) The method according to claim 42, wherein immobilization of a biospecific affinity reactant by covalent binding is to the hydrophilic groups on the Capturer particles.[--]

[--]44. (Amended) The method according to claim 42, wherein immobilization of a [complex] mixture of biospecific affinity reactants is to the hydrophilic groups on the Capturer particles.[--]

[--]45. (Amended) The method according to claim 42, wherein immobilization of a [complex] mixture of biospecific affinity reactants found in allergen extracts is to the hydrophilic groups on the Capturer particles.[--]

[--]46. (Amended) The method according to claim 42, wherein immobilization of a [complex] mixture of biospecific affinity reactants found in biological material used to detect autoantibodies is to the hydrophilic groups on the Capturer particles.[--]

[--]47. (Amended) The method according to claim 42, wherein the hydrophilic [grops] groups are hydroxy, carboxy, amino or sulphonate groups.[--]

[--]48. (Amended) The method according to claim 42, wherein the analyte is an antibody of IgE or IgG type with specificity to allergens.[--]

[--]49. (Amended) The method according to claim 42, wherein the analyte is an antibody of IgG, IgM or IgA type with specificity to autoantigens.[--]

[--]50. (Amended) The method according to claim 42, wherein the particles anchoring the Capturer have a size in the range of 0.1-100 μm and [which is smaller than a smallest inner dimension of] the flow channels of the matrix have a smallest inner dimension in the range of 0.4-100 μm.[--]

[--]51. (Amended) The method according to claim 42, wherein the particles which anchor the Capturer have a size in the range of 0.1-1000 μm.[--]

[--]52. (Amended) The method according to claim 42, wherein the particles which anchor the Capturer have a size in the range of 0.1-100 μm.[--]

[--]53. (Amended) The method according to claim 42, wherein the labeled particles in the Reactant* have a diameter in the range of 0.01-5 μm.[--]

[--]54. (Amended) The method according to claim 42, wherein the flow channels have a smallest inner diameter in the range of 0.4-1000 μm.[--]

[--]55. (Amended) The method according to claim 42, wherein the flow channels have a smallest inner dimension in the range of 0.4-100 μm.[--]

[--]56. (Amended) The method according to claim 42, wherein the labeled particles are fluorescent or coloured.[--]

[--]57. (Amended) The method according to claim 42, wherein the Reactant* is predeposited in the matrix upstream of the DZ.[--]

[--]58. (Amended) The method according to claim 57, wherein the Reactant* is predeposited in the matrix upstream of a sample application site.[--]

[--]59. (Amended) The method according to claim 42, wherein the particles which anchor the Capturer to the matrix are a synthetic polymer, a semisynthetic polymer or a biopolymer, which on its surface exhibits hydrophilic groups.[--]

[--]60. (Amended) The method according to claim 42, wherein the Reactant* is captured in the DZ by formation of a ternary complex of Reactant'[--]-analyte[--]-Reactant*, wherein the Reactant* binds to the analyte simultaneously or in sequence and Reactant' is the firmly anchored Capturer or a reactant to which the Capturer [may bind] <u>is capable of binding</u> by biospecific affinity.[--]

[--]61. (Amended) The method according to claim 60, wherein the analyte is an antigen and the Reactant' and Reactant* are antibodies with specificity for epitopes on the analyte.[--]

[--]62. (Amended) The method according to claim 42, wherein the method is performed in connection with diagnosing allergy or autoimmune disease.[--]

[--]63. (Amended) A test kit when used for performing analytical methods in a flow matrix, which methods utilize biospecific affinity reactions to detect an analyte in a sample, which kit comprises (i) a flow matrix having a detection zone (DZ), in which there is a firmly anchored biospecific affinity reactant (Capturer), and (ii) and analytically detectable reactant (Reactant*),

wherein

A) the Reactant* has labeled particles as an analytically detectable group, and

B) the Capturer is anchored to the matrix [via] by immobilized particles which exhibit hydrophilic groups on their surface, wherein the particles anchoring the Capturer have a diameter smaller than a smallest inner dimension of the flow channels of the flow matrix and do not interfere with detection of Reactant* in the detection zone.[--]

[--]64. (Amended) The kit according to claim 63, wherein immobilization of a biospecific affinity reactant by covalent binding is to the hydrophilic groups on the Capturer particles.[--]

[--]65. (Amended) The kit according to claim 63, wherein immobilization of a complex mixture of biospecific affinity reactants is to the hydrophilic groups on the Capturer particles.[--]

[--]66. (Amended) The kit according to claim 63, wherein immobilization of a complex mixture of biospecific affinity reactants found in allergen extracts is to the hydrophilic groups on the Capturer particles.[--]

[--]67. (Amended) The kit according to claim 63, wherein immobilization of a complex mixture of biospecific affinity reactants found in biological material used to detect autoantibodies is to the hydrophilic groups on the Capturer particles.[--]

[--]68. (Amended) The kit according to claim 63, wherein the hydrophilic groups are hydroxy, carboxy, amino or sulphonate groups.[--]

[--]69. (Amended) The kit according to claim 63, wherein the analyte is an antibody of IgE or IgG type with specificity to allergens.[--]

[--]70. (Amended) The kit according to claim 63, wherein the analyte is an antibody of IgG, IgM or IgA type with specificity to autoantigens.[--]

[--]71. (Amended) The kit according to claim 63, wherein the particles anchoring the Capturer have a size in the range of 0.1-100 μm and [which is smaller than a smallest inner dimension of] the flow channels of the matrix have a smallest inner dimension in the range of 0.4-100 μm. [--]

[--]72. (Amended) The kit according to claim 63, wherein the particles which anchor the Capturer have a size in the range of 0.1-1000 μm.[--]

[--]73. (Amended) The kit according to claim 63, wherein the particles which anchor the Capturer have a size in the range of 0.1-100 μm.[--]

[--]74. (Amended) The kit according to claim 63, wherein the labeled particles in the Reactant* have a diameter in the range of 0.01-5 μm.[--]

[--]75. (Amended) The kit according to claim 63, wherein the flow channels have a smallest inner dimension in the range of 0.4-1000 μm.[--]

[--]76. (Amended) The kit according to claim 63, wherein the flow channels have a smallest inner dimension in the range of 0.4-100 μm.[--]

[--]77. (Amended) The kit according to claim 63, wherein the labeled particles are fluorescent or coloured.[--]

[--]78. (Amended) The kit according to claim 63, wherein the Reactant* is predeposited in the matrix upstream of the DZ.[--]

[--]79. (Amended) The kit according to claim 78, wherein the Reactant* is predeposited in the matrix upstream of a sample application site.[--]

[--]80. (Amended) The kit according to claim 63, wherein the particles which anchor the Capturer to the matrix are a synthetic polymer, a semisynthetic polymer or a biopolymer, which on its surface exhibits hydrophilic groups.[--]

[--]81. (Amended) The kit according to claim 63, wherein the Reactant* is captured in the DZ by formation of a ternary complex of Reactant'[--]-analyte[--]-Reactant*, wherein the Reactant* binds to the analyte simultaneously or in sequence and Reactant' is the firmly anchored Capturer or a reactant to which the Capturer [may bind] <u>is capable of binding</u> by biospecific affinity.[--]

[--]82. (Amended) The kit according to claim 81, wherein the analyte is an antigen and the Reactant' and Reactant* are antibodies with a specificity for epitopes on the analyte.[--]

[--]83. (Amended) The kit according to claim 63, wherein the method is performed in connection with diagnosing allergy or autoimmune disease.[--]